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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 529**

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# Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The supplemental NADA provides for use of progesterone intravaginal inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

**DATES:** This rule is effective [*insert date of publication in the* **Federal Register**].

**FOR FURTHER INFORMATION CONTACT:** Harlan J. Howard, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0231, e-mail: *hhoward@cvm.fda.gov.*

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001–0199 filed a supplement to NADA 141–200 that provides for use of EAZI–BREED CIDR Progesterone Intravaginal Inserts for synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus. The NADA is approved as of July 29, 2003, and the regulations are amended in 21 CFR 529.1940 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning July 29, 2003.

The agency has determined under 21 CFR 25.33(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects in 21 CFR Part 529**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

## PART 529–CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Section 529.1940 is amended in paragraph (e)(3) in the first sentence by removing the phrase "; or in lactating dairy cows"; and by revising paragraphs (d)(1), (d)(2), (e)(1), and (e)(2) to read as follows:

**§ 529.1940 Progesterone intravaginal inserts.**

* * * * *

(d) * * *

(1) Product labeling shall bear the following warnings: "Avoid contact with skin by wearing latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed of in accordance with applicable local, State, and Federal regulations."

(2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period when used for indications listed in paragraph (e)(2)(i) of this section. See § 522.690(c) of this chapter.

* * * * *

(e) * * *

(1) *Amount.* Administer one intravaginal insert per animal for 7 days. When used for indications listed in paragraph (e)(2)(i) of this section, administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) as a single intramuscular injection one day prior to insert removal.

(2) *Indications for use*—(i) For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.

(ii) For synchronization of the return to estrus in lactating dairy cows inseminated at the immediately preceding estrus.

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Dated: 09-24-03
September 24, 2003.

Steven D. Vaughn DVM

Steven D. Vaughn,
Director,
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Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
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